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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/531,822

10/24/2005

Mark Brister

PA1187

3938

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MEDTRONIC VASCULAR, INC.
IP LEGAL DEPARTMENT
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EXAMINER

ADAMS, AMANDA S

ART UNIT

PAPER NUMBER

3731

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

12/18/2006

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/531,822	Applicant(s) BRISTER, MARK	
	Examiner Amanda Adams	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/28/06.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-25 is/are pending in the application.
- 4a) Of the above claim(s) 2 and 7 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-6 and 8-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 April 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>4.18.05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claims **1, 3-6, 8-11, 13, 14, 17, 18, and 20-22** are rejected under 35 U.S.C. 102(e) as being anticipated by Tedeschi (US 20030204238).

The applied reference has a common assignee with the instant application.

Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

3. Regarding **claims 1, 6, and 22**, Tedeschi discloses the invention substantially as claimed comprising a catheter delivery system (par. 22), a stent with a first and second discrete region (par. 34), a first coating section disposed on the first region and comprising a first polymer, and a second coating section disposed on the second region and comprising a second polymer (par. 34).

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4. Regarding **claims 3, 4, 8, and 9**, Tedeschi discloses that the first coating section includes a first therapeutic agent and that the second coating section includes a second therapeutic agent (par. 23 and 28).

5. Regarding **claims 5 and 10**, Tedeschi discloses that the first and second regions form a striped ring pattern (fig. 2 [218] and [216] form banded regions).

6. Regarding **claims 11 and 18**, Tedeschi discloses the method substantially as claimed including the stent with first and second regions as disclosed above, mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution (par. 23), applying the first polymer solution to the first region to form a first coating section (par. 27) and also performing these steps for the second polymer, second therapeutic agent, and second region (par. 27).

7. Regarding **claims 13 and 20**, Tedeschi discloses curing the first and second polymer solutions (par. 32).

8. Regarding **claims 14, 17, and 21**, Tedeschi discloses mounting the stent in a coating fixture and spraying the first polymer solution on the first region (par. 27).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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1. Claims **12, 19, and 23-25** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tedeschi (US 20030204238) in view of Richter (US 2002/0010505).
2. Regarding **claims 12 and 19**, Tedeschi discloses the invention substantially as claimed except for failing to disclose applying the first and second polymers to their respective regions of the stent simultaneously. However, Richter teaches a method of applying a coating, referred to as masking, whereby the coating can be simultaneously applied to multiple portions of the stent (paragraph 27). This shows that it is old and well-known to apply a coating to more than one region at a time, and can be used even when the coatings are applied by other methods, and when the coatings are therapeutic agents mixed with polymers and solvents, so that a stent can deliver the therapeutic agents to the appropriate part of a vessel in relation to the stent. Therefore it would have been obvious to coat more than one region at a time with a therapeutic agent mixed with a polymer, also in order to provide a more efficient method of manufacturing.
3. Regarding **claim 23**, Tedeschi discloses the invention substantially as claimed above except for failing to disclose that the discrete first and second regions are separated by a bare section. However, Richter teaches a stent that has a coating on two discrete regions that are separated by an uncoated region (figure 3A). Separation of coated regions such as this allow delivery of therapeutic substances to specifically designated areas of the blood vessel. Therefore, it would have been obvious to apply a therapeutic substance such as those disclosed by Tedeschi in the discrete regions separated by a bare region as shown in the device of Richter.

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4. Regarding claims **24 and 25**, due to lack of criticality in the applicant's specification, the distances between discrete coated regions serve no particular purpose and provide no additional benefit as opposed to any other specific distances. Therefore, it would have been obvious to arbitrarily choose these distances because they are both within the scope of the size of an intravascular stent.
5. Claims **15 and 16** are rejected under 35 U.S.C. 103(a) as being unpatentable over Tedeschi (US 20030204238) in view of Castro et al (US 6,616,765).
6. Tedeschi discloses the method substantially as claimed above but fails to disclose the following which is taught by Castro et al. Castro et al teach mounting the stent in a coating fixture which is a computerized numerically controlled machine (column 7, lines 12-36), and spraying the first polymer solution on the first region by spraying, inkjet spraying, or inkjet printing (column 7, lines 42-45). By using a numerically controlled machine to deposit the polymer solutions, the solution can be deposited in precise locations at a precise thickness, appropriate for its intended use. In addition, micro-spraying and ink-jet praying are old and well-known methods of spraying. Therefore it would have been obvious to use a numerically-controlled machine to micro-spray or ink-jet spray the polymer solution onto the stent.

Response to Arguments

7. Applicant's arguments, regarding the IDS, filed September 28, 2006, have been fully considered and are persuasive. The objection of the IDS has been withdrawn.

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8. Applicant's arguments with respect to claims 1-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amanda Adams whose telephone number is (571) 272-5577. The examiner can normally be reached on M-F, 8:00am-5:00pm, alternate Fridays off.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ASA ASA 11/29/06


GLENN K. DAWSON
PRIMARY EXAMINER